PATENT

Docket No.: CL/V-32902A/CVA

CLAIM AMENDMENTS

Please cancel claims 65-83 without prejudice to filing a divisional application containing the same.

- 1. (Original) A method for determining the fertility status of a current ovulation cycle of a female human, comprising the steps of: (a) monitoring variation in tear concentration of at least one hormone of relevance to female fertility; and (b) evaluating the correspondence of the variation in tear concentration of said hormone to onset of the transition phase, fertile phase, ovulation, or infertile phase of a menstrual cycle in said female human, wherein the step of monitoring is performed by periodically collecting a tear fluid from the female human and then determining the tear concentration of said hormone.
- (withdrawn) The method of claim 1, wherein the tear fluid is collected by the use of a tear-collecting device selected from the group consisting of a glass capillary tube and a hydrogel strip.
- 3. (withdrawn) The method of claim 2, wherein said tear-collecting device is a hydrogel strip, wherein said strip has a first end and an opposite second end, wherein said strip is made of a hydrogel material in substantially dry state and is characterized by having a substantially uniform swelling along that hydrogel strip from the first end to the second end when fully wicked by a tear fluid and by having a correlation between the volume of tear uptake by that strip and the length of a tear-wicked end portion of that strip.
- 4. (withdrawn) The method of claim 2, wherein the tear fluid is collected daily upon waking or at approximately a fixed time in the morning.
- 5. (Original) The method of claim 1, wherein the tear fluid is collected daily by having the female human wear a contact lens on an eye for at least 30 minutes and then by removing the contact lens from the eye.
- 6. (Original) The method of claim 5, wherein the tear fluid is collected daily at the end of each day, after wearing for more than 6 hour.
- 7. (Original) The method of claim 5, wherein said contact lens is a soft contact lens, a hydrogel soft contact lens, or a daily disposable hydrogel soft contact lens.

8. (Original) The method of claim 5, wherein said contact lens is a contact lens capable of binding said hormone, wherein the contact lens includes: (1) surface charges present in a density sufficient to impart to the contact lens an increased adsorption of said hormone; (2) a coating comprising a receptor which binds specifically said hormone; (3) molecular imprints for said hormone; or (4) a core material that is prepared from a composition containing a receptor which binds specifically said hormone.

- 9. (Original) The method of claim 1, wherein the first collecting of tear fluid in the current cycle is made at the cessation of menses.
- 10. (Original) The method of claim 1, wherein the first collecting of tear fluid in the current cycle is made at least at 3 days following the onset of menses.
- 11. (Original) The method of claim 1, wherein said hormone is estrogen, and wherein a significant increase in its tear concentration or a determined estrogen tear concentration being higher than a threshold value, following the cessation of menses, is indicative of the onset of the fertile period.
- 12. (Original) The method of claim 1, wherein said hormone is LH, wherein detection of a LH surge or a determined LH tear concentration being higher than a threshold value, indicates that the female human will no longer be fertile four days hence (3 days after ovulation).
- 13. (Original) The method of claim 1, wherein said hormone is progesterone, wherein the end of the fertile period can be predicted by detecting a significant increase in progesterone tear concentration or by detecting a progesterone tear concentration being higher than a threshold value following the cessation of menses.
- 14. (Original) The method of claim 1, wherein at least two of estrogen, LH and progesterone are monitored to determine the status of a menstrual cycle of the female human.
- 15. (Original) The method of claim 14, wherein estrogen and progesterone are monitored to determine the status of a menstrual cycle of the female human.
- 16. (Original) The method of claim 15, wherein the estrogen is estradiol, wherein a significant increase in the tear concentration ratio of estradiol to progesterone or a determined value of the tear concentration ratio of estradiol to progesterone being higher than a threshold value, following the cessation of menses, is indicative of the onset of the fertile period.

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17. (Original) A method for determining the fertility status of a current ovulation cycle of a female human, comprising a series of steps performed at least once per day for at least several days preceding and following ovulation, said steps comprising: (a) collecting a tear fluid from the female human; (b) determining variation in tear concentration of at least one hormone of relevance to female fertility to establish variation in tear concentration of said hormone; and (c) evaluating the correspondence of the variation in tear concentration of said hormone to onset of the fertile phase, ovulation, or infertile phase of a menstrual cycle in said female human.

- 18. (withdrawn) The method of claim 17, wherein the tear fluid is collected by the use of a tear-collecting device selected from the group consisting of a glass capillary tube and a hydrogel strip.
- 19. (withdrawn) The method of claim 18, wherein the tear fluid is collected daily upon waking or at approximately a fixed time in the morning.
- 20. (withdrawn) The method of claim 18, wherein said tear-collecting device is a hydrogel strip, wherein said strip has a first end and an opposite second end, wherein said strip is made of a hydrogel material in substantially dry state and is characterized by having a substantially uniform swelling along that hydrogel strip from the first end to the second end when fully wicked by a tear fluid and by having a correlation between the volume of tear uptake by that strip and the length of a tear-wicked end portion of that strip.
- 21. (Original) The method of claim 17, wherein the tear fluid is collected daily by having the female human wear a contact lens on an eye for at least 30 minutes and then by removing the contact lens from the eye.
- 22. (Original) The method of claim 21, wherein the tear fluid is collected daily at the end of each day, after wearing for more than 6 hour.
- 23. (Original) The method of claim 21, wherein said contact lens is a soft contact lens, a hydrogel soft contact lens, or a daily disposable hydrogel soft contact lens.
- 24. (Original) The method of claim 21, wherein said contact lens is a contact lens capable of binding said hormone, wherein the contact lens includes: (1) surface charges present in a density sufficient to impart to the contact lens an increased adsorption of said hormone; (2) a coating comprising a receptor which binds specifically said hormone; (3)

molecular imprints for said hormone; or (4) a core material that is prepared from a composition containing a receptor which binds specifically said hormone.

- 25. (Original) The method of claim 17, wherein said hormone is estrogen, and wherein a significant increase in its tear concentration or a determined estrogen tear concentration being higher than a threshold value, following the cessation of menses, is indicative of the onset of the fertile period.
- 26. (Original) The method of claim 17, wherein said hormone is LH, wherein detection of a LH surge or a determined LH tear concentration being higher than a threshold value, indicates that the female human will no longer be fertile four days hence (3 days after ovulation).
- 27. (Original) The method of claim 17, wherein said hormone is progesterone, wherein the end of the fertile period can be predicted by detecting a significant increase in progesterone tear concentration or by detecting a progesterone tear concentration being higher than a threshold value following the cessation of menses.
- 28. (Original) The method of claim 17, wherein at least two of estrogen, LH and progesterone are monitored to determine the status of a menstrual cycle of the female human.
- 29. (Original) The method of claim 28, wherein estrogen and progesterone are monitored to determine the status of a menstrual cycle of the female human.
- 30. (Original) The method of claim 29, wherein the estrogen is estradiol, wherein a significant increase in the tear concentration ratio of estradiol to progesterone or a determined value of the tear concentration ratio of estradiol to progesterone being higher than a threshold value, following the cessation of menses, is indicative of the onset of the fertile period.
- 31. (Original) The method of claim 17, further comprising conducting at least one test for the tear concentration of said hormone in the period from day 1 up to and including day 7 calculated from the onset of menses, to establish a base concentration value or signal for said hormone in the current cycle.
- 32. (Original) The method of claim 31, wherein the base concentration value is established from test(s) conducted on day 5 and/or day 6.

33. (Original) A birth control method, comprising the steps of: (a) monitoring variation in tear concentration of at least one hormone of relevance to female fertility; (b) evaluating the correspondence of the variation in tear concentration of said hormone to onset of the fertile phase, ovulation, and/or terminal infertile period of a menstrual cycle in said female human; and (c) causing said female human to avoid exposure to fertilization beginning at least at the onset of the fertile phase and ending day "+2" relative to the day of actual ovulation, wherein the step of monitoring is performed by periodically collecting a tear fluid from the female human and then determining the tear concentration of said hormone.

- 34. (withdrawn) The method of claim 33, wherein the tear fluid is collected by the use of a tear-collecting device selected from the group consisting of a glass capillary tube and a hydrogel strip.
- 35. (withdrawn) The method of claim 34, wherein the tear fluid is collected daily upon waking or at approximately a fixed time in the morning.
- 36. (withdrawn) The method of claim 34, wherein said tear-collecting device is a hydrogel strip, wherein said strip has a first end and an opposite second end, wherein said strip is made of a hydrogel material in substantially dry state and is characterized by having a substantially uniform swelling along that hydrogel strip from the first end to the second end when fully wicked by a tear fluid and by having a correlation between the volume of tear uptake by that strip and the length of a tear-wicked end portion of that strip.
- 37. (Original) The method of claim 33, wherein the tear fluid is collected daily by having the female human wear a contact lens on an eye for at least 30 minutes and then by removing the contact lens from the eye.
- 38. (Original) The method of claim 37, wherein the tear fluid is collected daily at the end of each day, after wearing for more than 6 hour.
- 39. (Original) The method of claim 37, wherein said contact lens is a soft contact lens, a hydrogel soft contact lens, or a daily disposable hydrogel soft contact lens.
- 40. (Original) The method of claim 37, wherein said contact lens is a contact lens capable of binding said hormone, wherein the contact lens includes: (1) surface charges present in a density sufficient to impart to the contact lens an increased adsorption of said hormone; (2) a coating comprising a receptor which binds specifically said hormone; (3)

molecular imprints for said hormone; or (4) a core material that is prepared from a composition containing a receptor which binds specifically said hormone.

- 41. (Original) The method of claim 33, wherein the first collecting of tear fluid in the current cycle is made at the cessation of menses.
- 42. (Original) The method of claim 33, wherein the first collecting of tear fluid in the current cycle is made at least at 3 days following the onset of menses.
- 43. (Original) The method of claim 33, wherein said hormone is estrogen, and wherein a significant increase in its tear concentration or a determined estrogen tear concentration being higher than a threshold value, following the cessation of menses, is indicative of the onset of the fertile period.
- 44. (Original) The method of claim 33, wherein said hormone is LH, wherein detection of a LH surge or a determined LH tear concentration being higher than a threshold value, indicates that the female human will no longer be fertile four days hence (3 days after ovulation).
- 45. (Original) The method of claim 33, wherein said hormone is progesterone, wherein the end of the fertile period can be predicted by detecting a significant increase in progesterone tear concentration or by detecting a progesterone tear concentration being higher than a threshold value following the cessation of menses.
- 46. (Original) The method of claim 33, wherein at least two of estrogen, LH and progesterone are monitored to determine the status of a menstrual cycle of the female human.
- 47. (Original) The method of claim 46, wherein estrogen and progesterone are monitored to determine the status of a menstrual cycle of the female human.
- 48. (Original) The method of claim 47, wherein the estrogen is estradiol, wherein a significant increase in the tear concentration ratio of estradiol to progesterone or a determined value of the tear concentration ratio of estradiol to progesterone being higher than a threshold value, following the cessation of menses, is indicative of the onset of the fertile period.
- 49. (Original) A birth control method, comprising a series of steps performed at least once per day for at least several days preceding and following ovulation, said steps comprising: (a) collecting a tear fluid from the female human; (b) determining variation in

tear concentration of at least one hormone of relevance to female fertility to establish variation in tear concentration of said hormone; (c) evaluating the correspondence of the variation in tear concentration of said hormone to onset of the fertile phase, ovulation, and/or terminal infertile period of a menstrual cycle in said female human; and (c) causing said female human to avoid exposure to fertilization beginning at least at the onset of the fertile phase and ending day "+2" relative to the day of actual ovulation.

- 50. (withdrawn) The method of claim 49, wherein the tear fluid is collected by the use of a tear-collecting device selected from the group consisting of a glass capillary tube and a hydrogel strip.
- 51. (withdrawn) The method of claim 50, wherein the tear fluid is collected daily upon waking or at approximately a fixed time in the morning.
- 52. (withdrawn) The method of claim 50, wherein said tear-collecting device is a hydrogel strip, wherein said strip has a first end and an opposite second end, wherein said strip is made of a hydrogel material in substantially dry state and is characterized by having a substantially uniform swelling along that hydrogel strip from the first end to the second end when fully wicked by a tear fluid and by having a correlation between the volume of tear uptake by that strip and the length of a tear-wicked end portion of that strip.
- 53. (Original) The method of claim 49, wherein the tear fluid is collected daily by having the female human wear a contact lens on an eye for at least 30 minutes and then by removing the contact lens from the eye.
- 54. (Original) The method of claim 53, wherein the tear fluid is collected daily at the end of each day, after wearing for more than 6 hour.
- 55. (Original) The method of claim 53, wherein said contact lens is a soft contact lens, a hydrogel soft contact lens, or a daily disposable hydrogel soft contact lens.
- 56. (Original) The method of claim 53, wherein said contact lens is a contact lens capable of binding said hormone, wherein the contact lens includes: (1) surface charges present in a density sufficient to impart to the contact lens an increased adsorption of said hormone; (2) a coating comprising a receptor which binds specifically said hormone; (3) molecular imprints for said hormone; or (4) a core material that is prepared from a composition containing a receptor which binds specifically said hormone.

- 57. (Original) The method of claim 49, wherein said hormone is estrogen, and wherein a significant increase in its tear concentration or a determined estrogen tear concentration being higher than a threshold value, following the cessation of menses, is indicative of the onset of the fertile period.
- 58. (Original) The method of claim 49, wherein said hormone is LH, wherein detection of a LH surge or a determined LH tear concentration being higher than a threshold value, indicates that the female human will no longer be fertile four days hence (3 days after ovulation).
- 59. (Original) The method of claim 49, wherein said hormone is progesterone, wherein the end of the fertile period can be predicted by detecting a significant increase in progesterone tear concentration or by detecting a progesterone tear concentration being higher than a threshold value following the cessation of menses.
- 60. (Original) The method of claim 49, wherein at least two of estrogen, LH and progesterone are monitored to determine the status of a menstrual cycle of the female human.
- 61. (Original) The method of claim 60, wherein estrogen and progesterone are monitored to determine the status of a menstrual cycle of the female human.
- 62. (Original) The method of claim 61, wherein the estrogen is estradiol, wherein a significant increase in the tear concentration ratio of estradiol to progesterone or a determined value of the tear concentration ratio of estradiol to progesterone being higher than a threshold value, following the cessation of menses, is indicative of the onset of the fertile period.
- 63. (Original) The method of claim 49, further comprising conducting at least one test for the tear concentration of said hormone in the period from day 1 up to and including day 7 calculated from the onset of menses, to establish a base concentration value or signal for said hormone in the current cycle.
- 64. (Original) The method of claim 63, wherein the base concentration value is established from test(s) conducted on day 5 and/or day 6.

65-83. (Canceled)

84. (Original) A method for determining the fertility status of a current ovulation cycle of a female non-human mammal, comprising the steps of: (a) monitoring variation in tear

concentration of at least one hormone of relevance to female fertility; and (b) evaluating the correspondence of the variation in tear concentration of said hormone to onset of the transition phase, fertile phase, ovulation, or infertile phase of a menstrual cycle in said female nonhuman mammal, wherein the step of monitoring is performed by periodically collecting a tear fluid from the female nonhuman mammal and then determining the tear concentration of said hormone.

- 85. (withdrawn) The method of claim 84, wherein the tear fluid is collected by the use of a tear-collecting device selected from the group consisting of a glass capillary tube and a hydrogel strip.
- 86. (Original) The method of claim 84, wherein said hormone is estrogen, and wherein a significant increase in its tear concentration or a determined estrogen tear concentration being higher than a threshold value, following the cessation of menses, is indicative of the onset of the fertile period.
- 87. (Original) The method of claim 84, wherein said hormone is LH, wherein detection of a LH surge or a determined LH tear concentration being higher than a threshold value, indicates that the female nonhuman mammal will no longer be fertile four days hence (3 days after ovulation).
- 88. (Original) The method of claim 84, wherein said hormone is progesterone, wherein the end of the fertile period can be predicted by detecting a significant increase in progesterone tear concentration or by detecting a progesterone tear concentration being higher than a threshold value following the cessation of menses.
- 89. (Original) The method of claim 84, wherein at least two of estrogen, LH and progesterone are monitored to determine the status of a menstrual cycle of the female nonhuman mammal.
- 90. (Original) The method of claim 89, wherein estrogen and progesterone are monitored to determine the status of a menstrual cycle of the female nonhuman mammal.
- 91. (Original) The method of claim 90, wherein the estrogen is estradiol, wherein a significant increase in the tear concentration ratio of estradiol to progesterone or a determined value of the tear concentration ratio of estradiol to progesterone being higher than a threshold value, following the cessation of menses, is indicative of the onset of the fertile period.